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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,061	05/19/2000	STEPHAN R. TARGAN	P-PM 4097	1578
23601	7590	04/19/2004	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/575,061	Applicant(s) TARGAN ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 2/5/04 is acknowledged and has been entered. Claims 2 and 3 have been amended. Claims 1-11 are pending. Claims 1-7 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. In light of Applicant's amendment, the rejection of claims 2-7 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for all of IgA outer membrane protein C (OmpC) antibody, anti-Saccharomyces antibody (ASCA), I-2 polypeptide antibody (I-2 antibody), and perinuclear anti-neutrophil antibodies (pANCA) as cumulative diagnostic markers for use in a method for diagnosing the presence of Crohn's disease, does not reasonably provide enablement for using only solely IgA anti-OmpC antibody as a

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diagnostic marker for diagnosing the presence of Crohn's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is being maintained for reasons of record.

Response to Arguments

4. Applicant's arguments filed 2/5/04 have been fully considered but they are not persuasive.

A) Applicant contends that the specification enables the invention as claimed. According to Applicant, the specification teaches methods of diagnosing Crohn's disease based on detection of IgA anti-OmpC antibodies without need or mention of any other detection marker. Applicant specifically argues that IgA OmpC reactivity itself detected 55% of patients having Crohn's disease, i.e. IgA anti-Ompc antibodies were present in 55% of patients having Crohn's disease, but in only 1 of 26 individuals without Crohn's disease. Applicant further argues that the claimed methods need not be highly sensitive, nor accurately diagnose all patients having Crohn's disease in order to be enabled. Applicant provides that anti-OmpC antibodies are present in large subset of patients with Crohn's disease; thus can serve to diagnose Crohn's disease where they are present.

In response, the number of subjects tested in order to determine the sensitivity of the claimed diagnostic method is not sufficient to establish adequate correlation between the presence of IgA anti-OmpC antibodies and the diagnosis of Crohn's

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disease. While Applicant found that anti-OmpC antibodies are present in a "large" subset of patients known to have Crohn's disease, i.e. 55% of 153 subjects, as confirmed by one or more of other detection markers used, nowhere in the specification provides that a presence of anti-OmpC antibodies in asymptomatic patients, not previously known to have Crohn's disease, is indicative of a diagnosis of Crohn's disease, which is encompassed by the claimed invention. Applicant's data in the specification has not provided that presence of IgA anti-OmpC antibody in any given population, defines a nexus with the diagnosis of Crohn's disease, absent further confirmation by any other detection marker of Crohn's disease. The Office is not a testing laboratory and is thus, not equipped to obtain actual evidentiary showing defining that such a nexus indeed exists between the presence of IgA anti-OmpC antibody and the indication diagnostic of Crohn's disease in a general population. Absent evidentiary showing that a correlation exists between the presence of IgA anti-OmpC antibody and actual diagnosis of Crohn's disease in 55% of any given population, the specification is not enabled for the recited claimed invention.

5. For reasons aforementioned, no claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
April 13, 2004 *gg*



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ /641